IC 25-26-14

Chapter 14. Wholesale Legend Drug Distributors

IC 25-26-14-1

Application of chapter

Sec. 1. (a) This chapter applies to any individual, partnership, limited liability company, corporation, or business firm:

(1) located in or outside Indiana; and

(2) engaging in the wholesale distribution of legend drugs in Indiana.

(b) Except as required by federal law or regulation, the requirements of this chapter do not apply to a manufacturer that is approved by the federal Food and Drug Administration. However, the board may adopt rules concerning manufacturers that the board considers appropriate and necessary.

(c) The requirements of this chapter do not apply to a medical gas manufacturer or distributor that only manufactures or distributes medical gases.

As added by P.L.182-1991, SEC.3. Amended by P.L.8-1993, SEC.394; P.L.212-2005, SEC.23; P.L.98-2006, SEC.12.

IC 25-26-14-1.5

"Adulterated" defined

Sec. 1.5. As used in this chapter, "adulterated" refers to a legend drug that:

(1) consists in whole or in part of a filthy, putrid, or decomposed substance;

(2) has been produced, prepared, packed, or held under unsanitary conditions and may have been contaminated or rendered injurious to health;

(3) has been subjected to conditions in the manufacture, processing, packing, or holding of the legend drug that do not conform to current standards of manufacturing to ensure that the legend drug is safe for use and possesses the identity, strength, quality, and purity characteristics that the legend drug is represented to possess;

(4) is contained in a container composed of a poisonous or deleterious substance that may render the legend drug injurious to health;

(5) bears or contains, for purposes of coloring only, a color additive that is unsafe;

(6) is of a different strength, quality, or purity from the official compendium standard for the legend drug; or

(7) does not meet the considerations of the federal Food, Drug, and Cosmetic Act.

As added by P.L.212-2005, SEC.24.

IC 25-26-14-1.7

"Authenticate" defined

Sec. 1.7. As used in this chapter, "authenticate" means to

affirmatively verify before distribution occurs that each transaction that is listed on:

(1) the pedigree of a legend drug; and

(2) other accompanying documentation for a legend drug;

has occurred.

As added by P.L.212-2005, SEC.25.

IC 25-26-14-1.8

"Authorized distributor" defined

Sec. 1.8. As used in this chapter, "authorized distributor" means a wholesale drug distributor with which a manufacturer has established an ongoing relationship to distribute the manufacturer's products. For purposes of this section, an ongoing relationship exists between a wholesale drug distributor, including any affiliated group (as defined in Section 1504 of the Internal Revenue Code) of which the wholesale distributor is a member, and a manufacturer if the wholesale drug distributor:

(1) has a written agreement currently in effect with the manufacturer evidencing an ongoing relationship;

(2) is listed on the manufacturer's current monthly updated list of authorized distributors; or

(3) has a verifiable account with the manufacturer and a minimal transaction or volume requirement limit of:

(A) five thousand (5,000) units per company in the previous twelve (12) months; or

(B) twelve (12) purchases at the manufacturer's minimum purchasing requirement per invoice in the previous twelve (12) months.

As added by P.L.212-2005, SEC.26.

IC 25-26-14-2

"Blood" defined

Sec. 2. As used in this chapter, "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-3

"Blood component" defined

Sec. 3. As used in this chapter, "blood component" means that part of blood separated by physical or mechanical means.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-3.7

"Chain drug warehouse" defined

Sec. 3.7. As used in this chapter, "chain drug warehouse" means a permanent physical location for drugs or devices, or both, that:

(1) is licensed as a wholesale distributor;

(2) acts as a central warehouse; and

(3) primarily performs intracompany sales and transfers of

legend drugs or devices to members of the same affiliated group that is under common ownership and control.

As added by P.L.98-2006, SEC.13.

IC 25-26-14-4

"Board" defined

Sec. 4. As used in this chapter, "board" refers to the Indiana board of pharmacy established under IC 25-26-13-3.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-4.1

"Co-licensed products" defined

Sec. 4.1. As used in this chapter, "co-licensed products" means pharmaceutical products:

(1) that have been approved by the federal Food and Drug Administration; and

(2) concerning which two (2) or more parties have the right to engage in a business activity or occupation concerning the pharmaceutical products.

As added by P.L.212-2005, SEC.27.

IC 25-26-14-4.2

"Compendium" defined

Sec. 4.2. As used in this chapter, "compendium" refers to:

(1) the United States Pharmacopoeia;

(2) the Homeopathic Pharmacopoeia of the United States;

(3) the National Formulary;

(4) a drug approved by the federal Food and Drug Administration; or

(5) a supplement to a document specified in subdivision (1), (2), or (3).

As added by P.L.212-2005, SEC.28.

IC 25-26-14-4.3

"Contraband" defined

Sec. 4.3. As used in this chapter, "contraband" refers to a legend drug:

(1) that is counterfeit;

(2) that is stolen;

(3) that is misbranded;

(4) that is obtained by fraud;

(5) that is purchased by a nonprofit institution for the nonprofit institution's own use and placed in commerce in violation of the own use agreement for the legend drug;

(6) for which a required pedigree does not exist; or

(7) for which a pedigree in existence:

(A) has been forged, counterfeited, or falsely created; or

(B) contains any altered, false, or misrepresented information.

As added by P.L.212-2005, SEC.29.

IC 25-26-14-4.4
"Counterfeit" defined

Sec. 4.4. As used in this chapter, "counterfeit" refers to a legend drug, or the container, seal, or labeling of a legend drug, that, without authorization, bears the trademark, trade name, or other identifying mark or imprint of a manufacturer, processor, packer, or distributor other than the person that manufactured, processed, packed, or distributed the legend drug.

As added by P.L.212-2005, SEC.30.

IC 25-26-14-4.5
"Deliver" defined

Sec. 4.5. As used in this chapter, "deliver" means the actual, constructive, or attempted transfer of a legend drug from one (1) person to another.

As added by P.L.212-2005, SEC.31.

IC 25-26-14-4.6
"Designated representative" defined

Sec. 4.6. As used in this chapter, "designated representative" means an individual who:

(1) is designated by a wholesale drug distributor;

(2) serves as the wholesale drug distributor's responsible individual with the board; and

(3) is actively involved in and aware of the actual daily operation of the wholesale drug distributor.

As added by P.L.212-2005, SEC.32.

IC 25-26-14-4.7
"Distribute" defined

Sec. 4.7. As used in this chapter, "distribute" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a legend drug, whether by passage of title or physical movement, or both. The term does not include the following:

(1) Dispensing or administering a legend drug.

(2) Delivering or offering to deliver a legend drug by a common carrier in the usual course of business as a common carrier.

(3) The provision of a legend drug sample to a patient by a:

(A) practitioner;

(B) health care professional acting at the direction and under the supervision of a practitioner; or

(C) hospital's or other health care entity's pharmacy that received the drug sample in accordance with this chapter and other applicable law to administer or dispense and that is acting at the direction of a practitioner;

licensed to prescribe the legend drug.

As added by P.L.212-2005, SEC.33.

IC 25-26-14-5
"Drug sample" defined

Sec. 5. As used in this chapter, "drug sample" means a unit of a legend drug that is not intended to be sold and is intended to promote the sale of the drug.
As added by P.L.182-1991, SEC.3.

IC 25-26-14-6
"Health care entity" defined

Sec. 6. As used in this chapter, "health care entity" means any organization or business that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care. The term does not include a pharmacy or wholesale drug distributor.
As added by P.L.182-1991, SEC.3. Amended by P.L.212-2005, SEC.34.

IC 25-26-14-6.5
"Label" defined

Sec. 6.5. As used in this chapter, "label" means a display of written, printed, or graphic matter on the immediate container of a legend drug.
As added by P.L.212-2005, SEC.35.

IC 25-26-14-6.6
"Labeling" defined

Sec. 6.6. As used in this chapter, "labeling" means labels and other written, printed, or graphic matter:

(1) on a legend drug or a legend drug's container or wrapper; or

(2) accompanying a legend drug.

As added by P.L.212-2005, SEC.36.

IC 25-26-14-7
"Legend drug" defined

Sec. 7. As used in this chapter, "legend drug" has the meaning set forth in IC 16-18-2-199. The term includes any human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to 21 U.S.C. 811 through 812. The term does not include a device or a device component, part, or accessory.
As added by P.L.182-1991, SEC.3. Amended by P.L.2-1993, SEC.147; P.L.212-2005, SEC.37.

IC 25-26-14-8
"Manufacturer" defined

Sec. 8. As used in this chapter, "manufacturer" means a person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a legend drug.
As added by P.L.182-1991, SEC.3.

IC 25-26-14-8.3
"Misbranded" defined

Sec. 8.3. As used in this chapter, "misbranded" means that a legend drug's label:

(1) is false or misleading;

(2) does not bear the name and address of the manufacturer, packer, or distributor or does not contain an accurate statement of the quantities of active ingredients of the legend drug;

(3) does not show an accurate monograph for the legend drug; or

(4) does not comply with any other requirements of the federal Food, Drug, and Cosmetic Act.

As added by P.L.212-2005, SEC.38.

IC 25-26-14-8.5

"Normal distribution chain of custody" defined

Sec. 8.5. As used in this chapter, "normal distribution chain of custody" means the route that a legend drug travels:

(1) from a manufacturer to a wholesale drug distributor, to a pharmacy, and to a patient or a patient's agent;

(2) from a manufacturer to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent;

(3) from a manufacturer to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent;

(4) from a manufacturer to a third party logistics provider, to a wholesale drug distributor, to a pharmacy, and to a patient or a patient's agent;

(5) from a manufacturer to a third party logistics provider, to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent;

(6) from a manufacturer to a third party logistics provider, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent; or

(7) as prescribed by rules adopted by the board.

As added by P.L.212-2005, SEC.39.

IC 25-26-14-8.7

"Pedigree" defined

Sec. 8.7. As used in this chapter, "pedigree" means a statement or record in a written or an electronic form that is approved by the board, that:

(1) records each wholesale distribution of a legend drug from the sale by the manufacturer that leaves the normal distribution chain of custody and that includes information designated by the board through rules for each transaction; or

(2) complies with a legend drug pedigree law or regulation in another state or United States territory that meets the pedigree requirements under this chapter.

As added by P.L.212-2005, SEC.40. Amended by P.L.98-2006,

SEC.14.

IC 25-26-14-9
"Person" defined

Sec. 9. As used in this chapter, "person" means an individual, a partnership, a business firm, a limited liability company, a corporation, or another entity, including a governmental entity.

As added by P.L.182-1991, SEC.3. Amended by P.L.8-1993, SEC.395; P.L.212-2005, SEC.41.

IC 25-26-14-9.2
"Practitioner" defined

Sec. 9.2. As used in this chapter, "practitioner" has the meaning set forth in IC 16-42-19-5.

As added by P.L.212-2005, SEC.42.

IC 25-26-14-9.3
"Repackage" defined

Sec. 9.3. As used in this chapter, "repackage" means changing the container, wrapper, quantity, or labeling of a legend drug to further the distribution of the legend drug.

As added by P.L.212-2005, SEC.43.

IC 25-26-14-10
"Sale" defined

Sec. 10. As used in this chapter, "sale" includes purchase, trade, or offer to sell, purchase, or trade.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-10.5
"Third party logistics provider" defined

Sec. 10.5. As used in this chapter, "third party logistics provider" means an entity that:

(1) provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the legend drug or have general responsibility to direct the legend drug's sale or disposition; and

(2) is licensed under this chapter.

As added by P.L.212-2005, SEC.44.

IC 25-26-14-11
"Wholesale distribution" defined

Sec. 11. As used in this chapter, "wholesale distribution" means to distribute legend drugs to persons other than a consumer or patient. The term does not include:

(1) a sale or transfer between a division, a subsidiary, a parent, an affiliated, or a related company under the common ownership and control of a corporate entity;

(2) the purchase or acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a

drug for the hospital's or health care entity's own use from the group purchasing organization or from other hospitals or health care entities that are members of the organization;

(3) the sale of a drug by a charitable organization described in Section 501(c)(3) of the Internal Revenue Code, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) the sale of a drug among hospitals or other health care entities that are under common control;

(5) the sale of a drug for emergency medical reasons, including transfers of legend drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, if the gross dollar value of the transfers does not exceed five percent (5%) of the total legend drug sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period;

(6) the sale of a drug or the dispensing of a drug pursuant to a prescription;

(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives;

(8) the sale of blood and blood components intended for transfusion;

(9) the sale of a drug by a retail pharmacy to a practitioner (as defined in IC 25-26-13-2) for office use, if the gross dollar value of the transfers does not exceed five percent (5%) of the retail pharmacy's total legend drug sales during any twelve (12) consecutive months;

(10) the sale of a drug by a retail pharmacy that is ending its business and liquidating its inventory to another retail pharmacy;

(11) drug returns by a hospital, health care entity, or charitable institution conducted under 21 CFR 203.23;

(12) the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use;

(13) the distribution of prescription drugs by the original manufacturer of the finished form of the prescription drug or the distribution of the co-licensed products by a partner of the original manufacturer of the finished form of the prescription drug; or

(14) drug returns that meet criteria established by rules adopted by the board.

As added by P.L.182-1991, SEC.3. Amended by P.L.33-1993, SEC.47; P.L.212-2005, SEC.45.

IC 25-26-14-12

"Wholesale drug distributor" defined

Sec. 12. As used in this chapter, "wholesale drug distributor" means a person engaged in wholesale distribution of legend drugs, including:

(1) manufacturers;

(2) repackers;
(3) own-label distributors;
(4) private-label distributors;
(5) jobbers;
(6) brokers;
(7) warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses;
(8) independent wholesale drug traders;
(9) retail and hospital pharmacies that conduct wholesale distributions; and
(10) reverse distributors.

The term does not include a common carrier or person hired solely to transport prescription drugs.

As added by P.L.182-1991, SEC.3. Amended by P.L.98-2006, SEC.15.

IC 25-26-14-13

Rules

Sec. 13. The board shall adopt rules under IC 4-22-2 that conform with wholesale drug distributor licensing guidelines adopted by the United States Food and Drug Administration (21 CFR 205), including rules:

(1) necessary to carry out the purposes of this chapter;
(2) that incorporate and set detailed standards for meeting each of the license prerequisites set forth in this chapter; and
(3) establishing reasonable fees to carry out this chapter.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-14

Accreditation and license for wholesale distribution of legend drugs

Sec. 14. (a) A person may not engage in wholesale distributions of legend drugs without:

(1) after December 31, 2005, obtaining and maintaining accreditation or certification from the National Association of Boards of Pharmacy's Verified Accredited Wholesale Distributor or an accreditation body approved by the board under subsection (g);
(2) obtaining and maintaining a license issued by the board; and
(3) paying any reasonable fee required by the board.

(b) The board may not issue or renew the license of a wholesale drug distributor that does not comply with this chapter.

(c) The board shall require a separate license for each facility or location where wholesale distribution operations are conducted.

(d) An agent or employee of any licensed wholesale drug distributor does not need a license and may lawfully possess pharmaceutical drugs when acting in the usual course of business or employment.

(e) The issuance of a license under this chapter does not affect tax liability imposed by the department of state revenue or the

department of local government finance on any wholesale drug distributor.

(f) The board may adopt rules that permit out-of-state wholesale drug distributors to obtain a license on the basis of reciprocity if:

(1) an out-of-state wholesale drug distributor possesses a valid license granted by another state and the legal standards for licensure in the other state are comparable to the standards under this chapter; and

(2) the other state extends reciprocity to wholesale drug distributors licensed in Indiana.

However, if the requirements for licensure under this chapter are more restrictive than the standards of the other state, the out-of-state wholesale drug distributor must comply with the additional requirements of this chapter to obtain a license under this chapter.

(g) The board may adopt rules under IC 4-22-2 to approve an accreditation body to:

(1) evaluate a wholesale drug distributor's operations to determine compliance with:

(A) professional standards;

(B) this chapter; and

(C) any other applicable law; and

(2) perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesale drug distributor.

As added by P.L.182-1991, SEC.3. Amended by P.L.90-2002, SEC.456; P.L.212-2005, SEC.46.

IC 25-26-14-14.5

Pedigree required

Sec. 14.5. After June 30, 2006, a wholesale drug distributor may not accept or deliver a legend drug without a current, accompanying pedigree as required under section 17 of this chapter.

As added by P.L.212-2005, SEC.47. Amended by P.L.98-2006, SEC.16.

IC 25-26-14-15

Information for grant and renewal of license; surety bond; inspection; reporting change in information

Sec. 15. (a) The board shall require the following minimum information from each wholesale drug distributor as part of the license described in section 14 of this chapter and as part of any renewal of such license:

(1) The name, full business address, and telephone number of the licensee.

(2) All trade or business names used by the licensee.

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of legend drugs.

(4) The type of ownership of operation.

(5) The name of each owner and operator of the licensee,

including:

(A) if an individual, the name, address, Social Security number, and date of birth of the individual;

(B) if a partnership, the name, address, Social Security number, and date of birth of each partner, and the name of the partnership and federal employer identification number;

(C) if a corporation:

(i) the name, address, Social Security number, date of birth, and title of each corporate officer and director;

(ii) the corporate names, the name of the state of incorporation, the federal employer identification number, and the name of the parent company, if any; and

(iii) the name, address, and Social Security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, unless the stock is traded on a major stock exchange and not traded over the counter;

(D) if a limited liability company, the name of each manager and member, the name and federal employer identification number of the limited liability company, and the name of the state where organized; and

(E) if a sole proprietorship, the full name, address, Social Security number, and date of birth of the sole proprietor and the name and federal employer identification number of the business entity.

(6) The name, address, and telephone number of the designated representative of each facility.

(7) Additional information concerning record keeping required under this chapter.

(b) The board shall require a wholesale drug distributor to post a surety bond of at least one hundred thousand dollars ($100,000), or an equivalent means of security acceptable to the board, including insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties that may be imposed by the board and any fees and costs that may be incurred by the board and that:

(1) are related to a license held by the wholesale drug distributor;

(2) are authorized under Indiana law; and

(3) the wholesale drug distributor fails to pay less than thirty (30) days after the penalties, fees, or costs become final.

However, a separate surety bond or an equivalent means of security is not required for a separate location or a company of the wholesale drug distributor.

(c) The board may make a claim against a bond or security posted under subsection (b) within one (1) year after the wholesale drug distributor's license is no longer valid or sixty (60) days after the conclusion of:

(1) an administrative or legal proceeding before or on behalf of the board that involves the wholesale drug distributor and results in penalties, fees, or costs described in subsection (b); or

(2) an appeal of a proceeding described in subdivision (1);

whichever occurs later.

(d) The board or the board's designee shall inspect each facility where wholesale distribution operations are conducted before initial licensure and periodically thereafter in accordance with a schedule determined by the board, but at least one (1) time in each three (3) year period.

(e) A wholesale drug distributor must publicly display or have readily available all licenses and the most recent inspection report administered by the board or the board's designee.

(f) A material change in any information in this section must be submitted to the board at the time of license renewal or within thirty (30) days from the date of the change, whichever occurs first.

As added by P.L.182-1991, SEC.3. Amended by P.L.8-1993, SEC.396; P.L.212-2005, SEC.48; P.L.98-2006, SEC.17.

IC 25-26-14-15.5

Repealed

(Repealed by P.L.98-2006, SEC.29.)

IC 25-26-14-16

Distributor qualifications; criminal history and financial background check

Sec. 16. (a) In reviewing, for purposes of licensure or renewal of a license under this chapter, the qualifications of persons who engage in wholesale distribution of legend drugs in Indiana, the board shall consider the following factors:

(1) A finding by the board that the applicant has:

(A) violated a law; or

(B) been disciplined by a regulatory agency for violating a law;

related to drug distribution in any state.

(2) A criminal conviction of the applicant.

(3) The applicant's past experience in the manufacture or distribution of legend drugs, including controlled substances.

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution.

(5) Suspension or revocation of any license held by the applicant or the applicant's owner or the imposition of sanctions against the applicant or the applicant's owner by the federal or a state or local government for the manufacture or distribution of any drugs, including controlled substances.

(6) Compliance with licensing requirements under previously granted licenses.

(7) Compliance with requirements to maintain and make available to the board or to federal, state, or local law enforcement officials those records required under this chapter.

(8) Any other factors or qualifications the board considers relevant to the public health and safety, including whether the

granting of the license would not be in the public interest.

(b) In reviewing an application for licensure or renewal of a license under this chapter, the board shall consider the results of criminal history and financial background checks for:

(1) the designated representative or the most senior individual responsible for facility operations, purchasing, and inventory control;

(2) the supervisor or the designated representative or the most senior individual under subdivision (1); and

(3) principals and owners with more than a ten percent (10%) interest in the wholesale drug distributor, if the wholesale drug distributor is a nonpublicly held company.

(c) The criminal history and financial background checks conducted under subsection (b) must:

(1) be conducted at the applicant's expense;

(2) include a criminal history for all current and previous states of residence of the applicant;

(3) include the criminal history in the federal district where the applicant currently resides;

(4) include information from the previous seven (7) years; and

(5) be approved by the board.

(d) An applicant shall provide and attest to:

(1) an affirmation that the applicant has not been involved in or convicted of any criminal or prohibited acts; or

(2) a statement providing a complete disclosure of the applicant's past criminal convictions and violations of state and federal laws;

regarding drugs.

As added by P.L.182-1991, SEC.3. Amended by P.L.212-2005, SEC.50; P.L.98-2006, SEC.18.

IC 25-26-14-16.5

Designated representative; application; experience requirement; continuing education

Sec. 16.5. (a) A wholesale drug distributor shall designate in writing on a form prescribed by the board a designated representative for each of the wholesale drug distributor's facilities licensed under this chapter.

(b) A designated representative shall submit to the board an application prescribed by the board and provide to the board the following:

(1) The date and place of birth of the designated representative.

(2) A list of the occupations, positions of employment, and offices held by the designated representative during the immediately preceding seven (7) years, including the principal business and address of the organization with which the occupation, position, or office was associated.

(3) A statement concerning whether the designated representative, during the immediately preceding seven (7) years, has been temporarily or permanently enjoined by a court

from violating a state or federal law regulating the possession, control, or distribution of legend drugs, including details of related events.

(4) A description of any involvement by the designated representative with a business that:

(A) manufactured, administered, prescribed, distributed, or stored legend drugs; and

(B) was named as a party in a lawsuit;

during the immediately preceding seven (7) years, including investments other than the ownership of stock in a publicly traded company or mutual fund.

(5) A description of any criminal offense of which the designated representative has been convicted, regardless of whether adjudication of guilt was withheld or whether the designated representative pleaded nolo contendere. If the designated representative indicates that a criminal conviction is under appeal, the designated representative shall submit to the board:

(A) a copy of the notice of appeal; and

(B) a copy of the final written order of disposition.

(6) A photograph of the designated representative taken within the immediately preceding thirty (30) days under procedures specified by the board.

(7) A list of the name, address, occupation, and date and place of birth of each member of the designated representative's immediate family, including the designated representative's spouse, children, parents, and siblings, and the spouses of the designated representative's children and siblings. Information collected under this subdivision is confidential.

(8) Any other information required by the board.

(c) A designated representative must have at least two (2) years of verifiable full-time managerial or supervisory experience in a pharmacy or with a wholesale drug distributor licensed under this chapter or in another state. The designated representative's responsibilities must have included record keeping, storage, and shipment of legend drugs.

(d) A designated representative shall not serve as the designated representative for more than one (1) wholesale drug distributor facility at any one (1) time.

(e) A designated representative shall be actively involved and aware of the actual daily operations of the wholesale drug distributor as follows:

(1) Be employed full time in a managerial position by the wholesale drug distributor.

(2) Be physically present at the wholesale drug distributor's facility during normal business hours, except when absent due to illness, family illness or death, scheduled vacation, or another authorized absence.

(3) Be aware of and knowledgeable about all policies and procedures pertaining to the operations of the wholesale drug

distributor.

(f) A designated representative must complete continuing education programs specified by the board regarding state and federal law relevant to the distribution, handling, and storage of legend drugs.

(g) A third party logistics provider must comply with this subsection until the third party logistics provider has obtained accreditation. A third party logistics provider must identify to the board a designated representative who is responsible for the facility's compliance with applicable state and federal law. The designated representative:

(1) may be a corporate employee or officer, outside counsel, or an outside consulting specialist with authority to help ensure compliance;

(2) may be responsible for multiple facilities; and

(3) is not required to be physically present at the facility.

As added by P.L.212-2005, SEC.51. Amended by P.L.98-2006, SEC.19.

IC 25-26-14-16.6

Designated agent; service of process

Sec. 16.6. (a) A wholesale drug distributor that:

(1) is licensed under this chapter;

(2) is located outside Indiana; and

(3) distributes legend drugs in Indiana;

shall designate an agent in Indiana for service of process.

(b) A wholesale drug distributor that does not designate an agent under subsection (a) is considered to have designated the secretary of state to be the wholesale drug distributor's true and lawful attorney, upon whom legal process may be served in an action or a proceeding against the wholesale drug distributor arising from the wholesale drug distributor's wholesale distribution operations.

(c) The board shall mail a copy of any service of process to a wholesale drug distributor by certified mail, return receipt requested, postage prepaid, at the address designated by the wholesale drug distributor on the application for licensure submitted under this chapter.

(d) Service of process on the secretary of state is sufficient in an action or a proceeding against a wholesale drug distributor that is not licensed under this chapter.

As added by P.L.212-2005, SEC.52.

IC 25-26-14-17

Applicant assurances as condition of license

Sec. 17. As a condition for receiving and retaining a wholesale drug distributor license issued under this chapter, an applicant must satisfy the board that the applicant has and will continuously maintain the following:

(1) Acceptable storage and handling conditions and facilities standards for each facility at which legend drugs are received,

stored, warehoused, handled, held, offered, marketed, or displayed, or from which legend drugs are transported, including:

(A) suitable construction of the facility and appropriate monitoring equipment to ensure that legend drugs in the facility are maintained in accordance with labeling or in compliance with official compendium standards;

(B) suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;

(C) adequate storage areas to provide appropriate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(D) a quarantine area for separate storage of legend drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, suspected counterfeit, otherwise unfit for distribution, or contained in immediate or sealed secondary containers that have been opened;

(E) maintenance of the facility in a clean and orderly condition;

(F) maintenance of the facility in a commercial, nonresidential building; and

(G) freedom of the facility from infestation.

(2) Security of each facility from unauthorized entry as follows:

(A) Entry into areas where legend drugs are held is limited to authorized personnel.

(B) Each facility is equipped with a security system that includes:

(i) an after hours central alarm or a comparable entry detection capability;

(ii) restricted premises access;

(iii) adequate outside perimeter lighting;

(iv) safeguards against theft and diversion, including employee theft and theft or diversion facilitated or hidden by tampering with computers or electronic records; and

(v) a means of protecting the integrity and confidentiality of data and documents and of making the data and documents readily available to the board and other state and federal law enforcement officials.

(3) A reasonable system of record keeping as follows:

(A) The system describes all the wholesale distributor's activities governed by this chapter for the three (3) year period after the disposition of each product, and all records are maintained for at least three (3) years after disposition of the legend drug to which the record applies.

(B) The system is reasonably accessible as determined by board rules in any inspection authorized by the board.

(C) The system provides a means to establish and maintain inventories and records of transactions regarding the receipt and distribution or other disposition of all legend drugs, including the following:

(i) For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is an authorized distributor, a pedigree for each distributed legend drug that leaves the normal distribution chain of custody, as determined by rules adopted by the board.

(ii) For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is not an authorized distributor, a pedigree for each distributed legend drug that leaves the normal chain of custody.

(iii) After January 1, 2007, and after consulting with the federal Food and Drug Administration, at the board's discretion, for each legend drug received and distributed by the wholesale drug distributor, an electronic pedigree developed in accordance with standards and requirements of the board to authenticate, track, and trace legend drugs. The standards and requirements of the board may indicate the information required to be part of the electronic pedigree.

(iv) Dates of receipt and distribution or other disposition of the legend drugs by the wholesale drug distributor.

(v) Availability for inspection and photocopying by any authorized official of a local, state, or federal governmental agency for three (3) years after the creation date of the inventories and records.

(D) Onsite electronic inventories and records are immediately available for inspection, and records kept at a central location apart from the inspection site and not electronically retrievable are available for inspection within two (2) working days after a request by an authorized official of a local, state, or federal governmental agency.

(E) The system maintains an ongoing list of persons with whom the wholesale drug distributor does business.

(F) The system provides for reporting counterfeit or suspected counterfeit legend drugs or counterfeiting or suspected counterfeiting activities to the board and the federal Food and Drug Administration.

(G) The system provides for mandatory reporting of significant shortages or losses of legend drugs to the board and the federal Food and Drug Administration, if applicable, if diversion is known or suspected.

(4) Written policies and procedures to which the wholesale drug distributor adheres for the receipt, security, storage, inventory, transport, shipping, and distribution of legend drugs, and that assure reasonable wholesale distributor preparation for, protection against, and handling of any facility security or operation problems, including the following:

(A) Facility security or operation problems caused by natural disaster or government emergency.

(B) Correction of inventory inaccuracies.

(C) Product shipping and receiving problems.

(D) Quarantine and return to the manufacturer or destruction in accordance with state and federal law of all outdated products and outdated or expired legend drugs, including appropriate documentation and witnessing.

(E) Appropriate disposition of returned goods.

(F) Product recalls.

(G) Identifying, recording, and reporting losses or thefts.

(H) Recalls and withdrawals of legend drugs due to:

(i) an action initiated by the federal Food and Drug Administration or another federal, state, or local governmental agency;

(ii) a volunteer action by the manufacturer to remove defective or potentially defective legend drugs from the market; or

(iii) an action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design.

(I) Disposition and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging are not used in counterfeiting activities, including necessary documentation and witnessing in accordance with state and federal law.

(J) Investigation of discrepancies in the inventory involving counterfeit, suspected counterfeit, contraband, or suspected contraband legend drugs and reporting of discrepancies within three (3) business days to the board and any other appropriate state or federal governmental agency.

(K) Reporting of criminal or suspected criminal activities involving the inventory of legend drugs to the board within three (3) business days.

(L) Conducting for cause authentication as required under sections 17.2 and 17.8 of this chapter.

(5) Written policies and procedures and sufficient inspection procedures for all incoming and outgoing product shipments, including the following:

(A) Upon receipt, visual examination of each shipping container in a manner adequate to identify the legend drugs in the container and to determine whether the legend drugs may be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, suspected counterfeit, damaged, or otherwise unfit for distribution.

(B) Upon receipt, review of records by the wholesale drug distributor for the acquisition of legend drugs for accuracy and completeness, considering the:

(i) total facts and circumstances surrounding each transaction involving the legend drugs; and

(ii) wholesale drug distributors involved.

(C) Quarantine of a legend drug considered to be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, suspected counterfeit, damaged, or otherwise

unfit for distribution until:

(i) examination and a determination that the legend drug is not outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution; or

(ii) the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired.

(D) Written policies and procedures to ensure that if the wholesale drug distributor determines that a legend drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug was acquired within three (3) business days.

(E) Written policies and procedures to ensure that if the immediate or sealed outer or secondary container or labeling of a legend drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor:

(i) quarantines the legend drug until the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired; and

(ii) provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug was acquired within three (3) business days.

(F) Written policies and procedures to ensure that a legend drug that has been opened or used, but is not adulterated, misbranded, counterfeit, or suspected counterfeit, is identified as such and quarantined until the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired.

(G) Written policies and procedures to ensure that:

(i) a legend drug that will be returned to a manufacturer or wholesale drug distributor is kept under proper conditions for storage, handling, transport, and shipment before the return; and

(ii) documentation showing that proper conditions were maintained is provided to the manufacturer or wholesale drug distributor to which the legend drug is returned.

(H) Inspection of each outgoing shipment for identity of the legend drugs and to ensure that the legend drugs have not been damaged in storage or held under improper conditions.

(I) Written policies and procedures to ensure that if conditions under which a legend drug has been returned to the wholesale drug distributor cast doubt on the legend drug's

safety, identity, strength, quality, or purity, the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired unless examination, testing, or other investigation proves that the legend drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a legend drug has been returned cast doubt on the legend drug's safety, identity, strength, quality, or purity, the wholesale drug distributor considers the conditions under which the legend drug has been held, stored, or shipped before or during the legend drug's return and the condition of the legend drug and the legend drug's container, carton, or labeling upon receipt of the returned legend drug.

(J) Written policies and procedures to ensure that contraband, counterfeit, or suspected counterfeit legend drugs, other evidence of criminal activity, and accompanying documentation are retained until a disposition is authorized by the board and the federal Food and Drug Administration.

(K) Written policies and procedures to ensure that any shipping, immediate, or sealed outer or secondary container or labeling, and accompanying documentation, suspected of or determined to be counterfeit or fraudulent, are retained until a disposition is authorized by the board and the federal Food and Drug Administration.

(6) Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.

(7) Written policies and procedures to provide for the secure and confidential storage of information with restricted access and to protect the integrity and confidentiality of the information.

(8) A pedigree as required under this chapter, including an electronic pedigree developed in accordance with standards and requirements of the board under subdivision (3)(C)(iii).

(9) Appropriate inventory management and control systems to:

(A) prevent; and

(B) allow detection and documentation of;

theft, counterfeiting, or diversion of legend drugs.

(10) If the wholesale drug distributor is involved in the distribution of controlled substances, registration with the federal Drug Enforcement Administration and the board and compliance with all laws related to the storage, handling, transport, shipment, and distribution of controlled substances.

(11) Isolation of controlled substances from noncontrolled substances and storage of the controlled substances in a secure area in accordance with federal Drug Enforcement Administration security requirements and standards.

(12) Technology and equipment that allow the wholesale drug distributor to authenticate, track, and trace legend drugs. The technology and equipment meet standards set by the board and are used as required by the board to conduct for cause and

random tracking, tracing, and authentication of legend drugs.

(13) Employment, training, and documentation of the training concerning the proper use of the technology and equipment required under subdivision (12).

(14) Packaging operations in accordance with an official compendium allowing the identification of a compromise in the integrity of the legend drugs due to tampering or adverse storage conditions.

As added by P.L.182-1991, SEC.3. Amended by P.L.212-2005, SEC.53; P.L.98-2006, SEC.20.

IC 25-26-14-17.2

For cause authentication

Sec. 17.2. (a) A wholesale drug distributor that purchases legend drugs from another wholesale drug distributor and has reason to believe that a legend drug purchased from the other wholesale drug distributor is counterfeit, suspected counterfeit, misbranded, or adulterated shall conduct a for cause authentication of each distribution of the legend drug back to the manufacturer.

(b) A wholesale drug distributor that has engaged in the distribution of a legend drug for which a purchasing wholesale drug distributor conducts a for cause authentication under subsection (a) shall provide, upon request, detailed information regarding the distribution of the legend drug, including the:

(1) date of purchase of the legend drug;

(2) lot number of the legend drug;

(3) sales invoice number of the legend drug; and

(4) contact information, including name, address, telephone number, and electronic mail address of the wholesale drug distributor that sold the legend drug.

(c) If a wholesale drug distributor conducts a for cause authentication under subsection (a) and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration, if applicable, not more than ten (10) business days after completing the attempted authentication.

(d) If a wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer under subsection (a), the wholesale drug distributor shall maintain records of the authentication for three (3) years and shall produce the records for the board and the federal Food and Drug Administration upon request.

As added by P.L.212-2005, SEC.54. Amended by P.L.98-2006, SEC.21.

IC 25-26-14-17.3

Repealed

(Repealed by P.L.98-2006, SEC.29.)

IC 25-26-14-17.8

Purchase from unlicensed wholesale drug distributor; requirements; for cause authentication; random authentication; quarantine

Sec. 17.8. (a) A wholesale drug distributor licensed under this chapter that purchases legend drugs from a wholesale drug distributor that is not licensed under this chapter shall act with due diligence as required under this section and rules adopted by the board. However, the due diligence requirements of this section do not apply to purchases from an unlicensed wholesale drug distributor that has obtained accreditation through the National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors program.

(b) Before the initial purchase of legend drugs from the unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall obtain the following information from the unlicensed wholesale drug distributor:

(1) A list of states in which the unlicensed wholesale drug distributor is licensed.

(2) A list of states into which the unlicensed wholesale drug distributor ships legend drugs.

(3) Copies of all state and federal regulatory licenses and registrations held by the unlicensed wholesale drug distributor.

(4) The unlicensed wholesale drug distributor's most recent facility inspection reports.

(5) Information regarding general and product liability insurance maintained by the unlicensed wholesale drug distributor, including copies of relevant policies.

(6) A list of other names under which the unlicensed wholesale drug distributor does business or has been previously known.

(7) A list of corporate officers and managerial employees of the unlicensed wholesale drug distributor.

(8) A list of all owners of the unlicensed wholesale drug distributor that own more than ten percent (10%) of the unlicensed wholesale drug distributor, unless the unlicensed wholesale drug distributor is publicly traded.

(9) A list of all disciplinary actions taken against the unlicensed wholesale drug distributor by state and federal agencies.

(10) A description, including the address, dimensions, and other relevant information, of each facility used by the unlicensed wholesale drug distributor for legend drug storage and distribution.

(11) A description of legend drug import and export activities of the unlicensed wholesale drug distributor.

(12) A description of the unlicensed wholesale drug distributor's procedures to ensure compliance with this chapter.

(13) A statement:

(A) as to whether; and

(B) of the identity of each manufacturer for which;

the unlicensed wholesale drug distributor is an authorized distributor.

(c) Before the initial purchase of legend drugs from an unlicensed

wholesale drug distributor, the licensed wholesale drug distributor shall:

(1) request that the board obtain and consider the results of a national criminal history background check (as defined in IC 10-13-3-12) through the state police department of all individuals associated with the unlicensed wholesale drug distributor as specified for licensure of a wholesale drug distributor under section 16(b) of this chapter; and

(2) verify the unlicensed wholesale drug distributor's status as an authorized distributor, if applicable.

(d) If an unlicensed wholesale drug distributor's facility has not been inspected by the board or the board's agent within three (3) years after a contemplated purchase described in subsection (a), the licensed wholesale drug distributor shall conduct an inspection of the unlicensed wholesale drug distributor's facility:

(1) before the initial purchase of legend drugs from the unlicensed wholesale drug distributor; and

(2) at least once every three (3) years unless the unlicensed wholesale drug distributor's facility has been inspected by the board, or the board's agent, during the same period;

to ensure compliance with applicable laws and regulations relating to the storage and handling of legend drugs. A third party may be engaged to conduct the site inspection on behalf of the licensed wholesale drug distributor.

(e) At least annually, a licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall ensure that the unlicensed wholesale drug distributor maintains a record keeping system that meets the requirements of section 17(3) of this chapter.

(f) If a licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor has reason to believe that a legend drug purchased from the unlicensed wholesale drug distributor is misbranded, adulterated, counterfeit, or suspected counterfeit, the licensed wholesale drug distributor shall conduct a for cause authentication of each distribution of the legend drug back to the manufacturer.

(g) An unlicensed wholesale drug distributor that has engaged in the distribution of a legend drug for which a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) shall provide, upon request, detailed information regarding the distribution of the legend drug, including the:

(1) date of purchase of the legend drug;

(2) lot number of the legend drug;

(3) sales invoice number of the legend drug; and

(4) contact information, including name, address, telephone number, and any electronic mail address of the unlicensed wholesale drug distributor that sold the legend drug.

(h) If a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) and is unable to authenticate each distribution of the legend drug, the licensed wholesale drug

distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration within ten (10) business days after completing the attempted authentication.

(i) If a licensed wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer under subsection (f), the licensed wholesale drug distributor shall maintain records of the authentication for three (3) years and shall provide the records to the board upon request.

(j) A licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall, at least annually, conduct random authentications of required pedigrees on at least ten percent (10%) of sales units of distributions of legend drugs that were purchased from unlicensed wholesale drug distributors.

(k) An unlicensed wholesale drug distributor from which a licensed wholesale drug distributor has purchased legend drugs shall cooperate with the random authentications of pedigrees under this section and provide requested information in a timely manner.

(l) If a wholesale drug distributor conducts a random authentication under subsection (j) and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

As added by P.L.212-2005, SEC.56. Amended by P.L.98-2006, SEC.22.

IC 25-26-14-17.9

Use of trade or business name

Sec. 17.9. A wholesale drug distributor licensed under this chapter may not use a trade name or business name identical to a trade name or business name used by an unrelated wholesale drug distributor licensed under this chapter.

As added by P.L.212-2005, SEC.57. Amended by P.L.98-2006, SEC.23.

IC 25-26-14-18

Denial of license; review of board action

Sec. 18. (a) Any applicant denied a license or renewal under this chapter has the right of review of the board's action under IC 4-21.5.

(b) An applicant that is denied the accreditation under section 14 of this chapter from an accreditation body that has entered into an agreement with the board has the right of review of the accreditation body's decision by the board.

As added by P.L.182-1991, SEC.3. Amended by P.L.98-2006, SEC.24.

IC 25-26-14-19

Inspection of premises; recordkeeping

Sec. 19. (a) A person authorized by the board may enter and inspect, during normal business hours, all open premises that appear to be used by a wholesale drug distributor.

(b) Wholesale drug distributors may keep records regarding purchase and sales transactions at a central location apart from the principal office of the wholesale drug distributor or the location where the drugs were stored and from which the drugs were shipped, if the records are made available for inspection within two (2) working days of a request by the board. The records may be kept in any form permissible under federal law applicable to legend recordkeeping.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-20

Employee qualifications

Sec. 20. A person employed in wholesale distribution must have appropriate education or experience to assume responsibility for positions related to compliance with licensing requirements.

As added by P.L.182-1991, SEC.3. Amended by P.L.212-2005, SEC.58; P.L.98-2006, SEC.25.

IC 25-26-14-21

Renewal of licenses; lapsed licenses

Sec. 21. (a) A wholesale drug distributor license expires at midnight of the renewal date specified by the Indiana professional licensing agency under IC 25-1-5-4 in each even-numbered year.

(b) The board shall mail renewal application forms to each licensed wholesale drug distributor before the first day of the month before the month in which the license expires. If an application for renewal has not been filed and the required fee paid before the license expiration date, the wholesale drug distributor license shall lapse and become void.

(c) A lapsed license may be reinstated only by meeting the requirements under IC 25-1-8-6.

(d) A wholesale drug distributor may not be open for business after the license has lapsed, until the renewal is completed.

As added by P.L.182-1991, SEC.3. Amended by P.L.269-2001, SEC.26; P.L.1-2006, SEC.465.

IC 25-26-14-21.5

Prohibitions; sanctions

Sec. 21.5. (a) A person may not perform, cause the performance of, or aid the performance of the following:

(1) The manufacture, repackaging, sale, delivery, holding, or offering for sale of a legend drug that is adulterated, misbranded, counterfeit, suspected counterfeit, or is otherwise unfit for distribution.

(2) The adulteration, misbranding, or counterfeiting of a legend drug.

(3) The receipt of a legend drug that is adulterated, misbranded,

stolen, obtained by fraud or deceit, counterfeit, or suspected counterfeit, and the delivery or proffered delivery of the legend drug for pay or otherwise.

(4) The alteration, mutilation, destruction, obliteration, or removal of the whole or a part of the labeling of a legend drug or the commission of another act with respect to a legend drug that results in the legend drug being misbranded.

(5) Forging, counterfeiting, simulating, or falsely representing a legend drug using a mark, stamp, tag, label, or other identification device without the authorization of the manufacturer.

(6) The purchase or receipt of a legend drug from a person that is not licensed to distribute legend drugs to the purchaser or recipient.

(7) The sale or transfer of a legend drug to a person that is not authorized under the law of the jurisdiction in which the person receives the legend drug to purchase or receive legend drugs from the person selling or transferring the legend drug.

(8) Failure to maintain or provide records as required under this chapter.

(9) Providing the board, a representative of the board, or a state or federal official with false or fraudulent records or making false or fraudulent statements regarding a matter related to this chapter.

(10) The wholesale distribution of a legend drug that was:

(A) purchased by a public or private hospital or other health care entity;

(B) donated or supplied at a reduced price to a charitable organization; or

(C) stolen or obtained by fraud or deceit.

(11) Obtaining or attempting to obtain a legend drug by fraud, deceit, misrepresentation, or engaging in fraud, deceit, or misrepresentation in the distribution of a legend drug.

(12) Failure to obtain, authenticate, or provide a required pedigree.

(13) The receipt of a legend drug through wholesale distribution without first receiving a required pedigree attested to as accurate and complete by the wholesale drug distributor.

(14) Distributing a legend drug that was previously dispensed by a retail pharmacy or distributed by a practitioner.

(15) Failure to report an act prohibited by this section.

(b) The board may impose the following sanctions if, after a hearing under IC 4-21.5-3, the board finds that a person has violated subsection (a):

(1) Revoke the wholesale drug distributor's license issued under this chapter if the person is a wholesale drug distributor.

(2) Assess a civil penalty against the person. A civil penalty assessed under this subdivision may not be more than ten thousand dollars ($10,000) per violation.

As added by P.L.212-2005, SEC.59.

IC 25-26-14-22

Violations of chapter; license revocation; penalties

Sec. 22. (a) The board, upon a showing of a violation of this chapter, may revoke, suspend, or limit a license issued under this chapter after a proceeding under IC 4-21.5.

(b) After a proceeding under IC 4-21.5, the board may assess a civil penalty against a licensed wholesale drug distributor of not more than one thousand dollars ($1,000) for each occurrence. If the licensed wholesale drug distributor fails to pay the civil penalty within the time specified by the board, the board may suspend the license without additional proceedings.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-23

Purchase from unlicensed person; offense

Sec. 23. A person that knowingly purchases or receives a legend drug from any source other than a person licensed under this chapter, including a wholesale distributor, manufacturer, pharmacy distributor, or pharmacy commits a Class A misdemeanor. A subsequent unrelated violation of this section is a Level 6 felony.

As added by P.L.182-1991, SEC.3. Amended by P.L.158-2013, SEC.286.

IC 25-26-14-24

Injunction

Sec. 24. (a) Upon application by the board, a circuit or superior court may grant an injunction, a restraining order, or other order to enjoin a person from offering to engage or engaging in the performance of any practices for which a permit or license is required by any applicable federal or state law including this chapter, upon a showing that the practices were or are likely to be performed or offered to be performed without a permit or license.

(b) An action brought under this section must be commenced either in the county where the conduct occurred or is likely to occur or in the county where the defendant resides.

(c) An action brought under this section is in addition to any other penalty provided by law and may be brought concurrently with other actions to enforce this chapter.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-25

Refusal of inspection; offense

Sec. 25. A wholesale drug distributor that fails to allow an authorized person to enter and inspect a facility as provided in section 19 of this chapter commits a Class A misdemeanor. However, the offense is a Level 6 felony if the person has a prior unrelated conviction for an offense under this section.

As added by P.L.182-1991, SEC.3. Amended by P.L.158-2013, SEC.287.

IC 25-26-14-26

Offenses

Sec. 26. (a) A person who knowingly or intentionally engages in the wholesale distribution of a legend drug without a license issued under this chapter commits a Level 6 felony.

(b) A person who engages in the wholesale distribution of a legend drug and:

(1) who, with intent to defraud or deceive:

(A) fails to obtain or deliver to another person a complete and accurate required pedigree concerning a legend drug before:

(i) obtaining the legend drug from another person; or

(ii) transferring the legend drug to another person; or

(B) falsely swears or certifies that the person has authenticated any documents related to the wholesale distribution of legend drugs;

(2) who knowingly or intentionally:

(A) destroys, alters, conceals, or fails to maintain a complete and accurate required pedigree concerning a legend drug in the person's possession;

(B) purchases or receives legend drugs from a person not authorized to distribute legend drugs in wholesale distribution;

(C) sells, barters, brokers, or transfers a legend drug to a person not authorized to purchase the legend drug in the jurisdiction in which the person receives the legend drug in a wholesale distribution;

(D) forges, counterfeits, or falsely creates a pedigree;

(E) falsely represents a factual matter contained in a pedigree; or

(F) fails to record material information required to be recorded in a pedigree; or

(3) who:

(A) possesses a required pedigree concerning a legend drug;

(B) knowingly or intentionally fails to authenticate the matters contained in the pedigree as required; and

(C) distributes or attempts to further distribute the legend drug;

commits a Level 6 felony.

As added by P.L.182-1991, SEC.3. Amended by P.L.212-2005, SEC.60; P.L.158-2013, SEC.288.

IC 25-26-14-27

Offenses

Sec. 27. A wholesale drug distributor that fails to comply with the conditions and requirements described in section 17, 17.2, 17.8, 17.9, or 20 of this chapter commits a Level 6 felony.

As added by P.L.182-1991, SEC.3. Amended by P.L.212-2005, SEC.61; P.L.98-2006, SEC.26; P.L.158-2013, SEC.289.